IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

CARL SELF ET AL.

Group Art Unit: 3623

Examiner: Alison L. Karmelek

Serial No.: 10/064,959

Filed: September 4, 2002

For: ONLINE METHOD AND SYSTEM FOR FACILITATING IMPROVEMENTS IN THE CONSISTENCY, DELIVERABILITY AND/OR MEASURABILITY OF LAUNCH PRACTICES

Attorney Docket No.: 81085447 (FMC 1413 PUS)

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Mail Stop Appeal Brief - Patents
Commissioner for Patents
U.S. Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an Appeal Brief from the final rejection of claims 1-20 of the Office Action mailed on November 14, 2007 for the above-identified patent application.

I. REAL PARTY IN INTEREST

The real party in interest is Ford Motor Company ("Assignee"), a corporation organized and existing under the laws of the state of Delaware, and having a place of business at The American Road, Dearborn, MI 48121, as set forth in the assignment recorded in the U.S. Patent and Trademark Office on September 4, 2002 at Reel 013050/Frame 0672.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals, interferences or judicial proceedings known to the Appellants, the Appellants' legal representative, or the Assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-20 are pending in this application. Claims 1-20 have been rejected and are the subject of this appeal.

IV. STATUS OF AMENDMENTS

The Appellants have not filed any amendments after the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present application includes three (3) independent claims, *i.e.*, claims 1, 11, and 15.

Claim 1 is directed to an online method for facilitating improved consistency, deliverability and/or measurability of a launch practice utilized in a product development launch cycle across a first launch program team during a first launch program and a second launch program team during a second launch program. (*e.g.*, p. 2, ll. 12-20.) The online method includes determining a launch practice item based on a set of key sources, wherein the launch practice item is determined by a committee separate from the first and second launch program teams. (*e.g.*, p. 2, l. 31 - p. 3, l. 2.) The online method further includes transmitting the launch practice item to an at least one member of the second launch program team. (*e.g.*, p. 2, ll. 32-33.) The at least one member of the second launch program team uses the launch practice item to improve consistency, deliverability and/or measurability of the launch practice during the second launch program. (*e.g.*, p. 3, ll. 3-5.)

Claim 11 is directed to an online system for facilitating improved consistency, deliverability and/or measurability of a launch practice utilized in a product development launch cycle across a first launch program team during a first launch program and a second launch program team during a second launch program. (*e.g.*, p. 2, ll. 12-20.) The system includes at least one server computer operably serving at least one client computer. (*e.g.*, p. 5, ll. 5-6.) The at least one server computer is configured to transmit a launch practice item to an at least one member of the first launch program team during the first launch program. (*e.g.*, p. 3, ll. 31-33.) The at least one member uses the defined launch practice item to improve consistency, deliverability and/or measurability of the launch practice. (*e.g.*, p. 4, ll. 6-8.) The at least one server computer is further configured to receive an at least one member observation regarding the launch practice item from the at least one member of the first launch program team. (*e.g.*, p. 3, l. 33 - p. 4, l. 1.) Moreover, the at least one server computer is configured to transmit a revised launch practice item and/or a new launch practice item implementing the at least one member observation to an at least one member of the second launch program team before the end of the second launch program if implementing the observation improves the consistency, deliverability and/or measurability of the launch practice. (*e.g.*, p. 4, ll. 1-5.)

Claim 15 is directed to an online system for facilitating improved consistency, deliverability and/or measurability of a launch practice utilized in a product development launch cycle across a first launch program team during a first launch program and a second launch program team during a second launch program. (*e.g.*, p. 2, ll. 12-20.) The system includes a means for transmitting a launch practice item to an at least one member of the first launch program team during the first launch program. (*e.g.*, p. 8, l. 8 - p. 11, l. 9.) The at least one member uses the defined launch practice item to improve consistency, deliverability and/or measurability of the launch practice. (*e.g.*, p. 11, l. 10 - p. 13, l. 14.) The system further includes a means for receiving an at least one member observation regarding the launch practice item from the at least one member of the first launch program team. (*e.g.*, p. 13, ll. 15-31.) Furthermore, the system includes a means for transmitting a revised launch practice item and/or a new launch

practice item implementing the at least one member observation to an at least one member of the second launch program team before the end of the second launch program if implementing the observation improves the consistency, deliverability and/or measurability of the launch practice. (*e.g.*, p. 13, l. 32 - p. 15, l. 21.)

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-2, 6 and 8-20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Appl. Pub. No. 2003/0105773, filed by Linde *et al.* (hereinafter "*Linde*"), in view of U.S. Patent Appl. Pub. No. 2003/0171897, filed by Bieda *et al.* (hereinafter "*Bieda*").

Claims 3-5 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Linde* and *Bieda* in view of U.S. Patent Appl. Pub. No. 2003/0040998, filed by Jordan Kogler *et al.* (hereinafter "*Jordan Kogler*").

Claim 7 stands rejected under 35 U.S.C. §103(a) as being unpatentable over *Linde*.

VII. ARGUMENT

Initially, it is noted that all of the pending claims 1-20 stand rejected as being obvious over the primary reference *Linde*, alone or in combination with other references. The MPEP states that in order to rely on a reference under 35 U.S.C. § 103, it must be analogous prior art. MPEP § 2141.01(a). Thus, the reference must be in the field of Appellants' endeavor, or if "in a field different from that of [Appellants'] endeavor...is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering [the] invention as a whole." *Id.* In that regard, *Linde* does not constitute analogous prior art.

In particular, the present application is directed to a quality management system for use during a product development launch cycle. One of ordinary skill in the art, particularly in the automotive industry referred to in the background, would recognize that a product development launch cycle corresponds to a timeline over which a new product or program (*e.g.*, new vehicle) is initially planned and defined up to its full production launch. (See, p. 6, ll. 11-21.) The product development launch cycle includes several phases, such as planning, product design and development verification, process design and development verification, product and process validation and launch. Each phase consists of several key milestones, including kick-off (KO), strategic intent (SI), program approval (PA), product readiness (PR), change cutoff (CC), launch ready (LR), launch sign-off (LS) and final sign-off (FS), or the like. *Id.* A product development launch cycle includes launch elements, which correspond to tasks or events relating to product development, that require completion prior to the start of production and are characterized by where they fall on the product development launch cycle. *Id.* As one of ordinary skill in the art would recognize, product launch elements may cover aspects such as supplier sourcing, design robustness, design testing and specification compliance, production process design, quality inspection standards, process capability, production capacity, product packaging, product testing and operator training, to name a few.

Quality management systems targeting the product development launch cycle provide a framework of policies, procedures, processes and techniques used in planning, developing and ultimately launching products in industry. The aim is to ensure products are designed and produced to meet or exceed customer requirements, by embedding awareness of quality in organizational processes within the project management framework. To this end, launch program teams - dedicated to a particular product, group of products or program - made up of design and product engineers, quality control personnel, manufacturing personnel, buyers, and program managers are enlisted to seeing a program through the planning phase to the launch phase. Various launch practices are employed and/or utilized by launch program teams during the product development launch cycle to attain the various engineering, manufacturing and

purchasing milestones using a disciplined approach, which is aimed at quality control to ensure products are designed and produced to meet or exceed customer requirements. In that regard, the present application is directed to an online system and method for facilitating improved consistency, deliverability and/or measurability of these launch practices.

Linde, on the other hand, is directed to a method for predicting prescription drug sales based on current market data. The end result, according to *Linde*, is the presentation of information regarding various marketing parameters. (*Linde*, ¶ [0085].) In that regard, various simulated market studies relating to a particular drug can be conducted using three pieces of current market information: (1) knowledge about the relevant target market; (2) information of market's unmet needs regarding previously known drugs for the target illness; and (3) quantifying the propensity of physicians to prescribe the particular drug as an alternative to competing drugs. (*Linde*, ¶¶ [0029] and [0086].) Numerical values corresponding to the three pieces of information estimated above form the basis of the calculations for predicting the "post-launch performance" of the drug, *i.e.*, future market share. (*Linde*, ¶¶ [0030]-[0031].) According to *Linde*, the simulated market studies help predict the number of "captured" patients based on various marketing choices relating to latent needs of a particular drug, such as price points, onset of action or side effects. (*Linde*, ¶ [0086].) The market share predictions obtained based on these choices helps identify the appropriate target market to focus on sales.

Accordingly, *Linde* is not in Appellants' field of endeavor. *Linde* is directed to performing market studies as a way to predict future sales, whereas the present application relates to a quality management/operating system and method for facilitating improved consistency, deliverability and/or measurability of launch practices during a product development launch cycle.

Moreover, *Linde* would not have logically commended itself to an inventor's attention in considering the invention as a whole. *Linde* is directed to the marketing and sales

of a product. In particular, *Linde* relates to predicting future sales performance based on estimations made with respect to current market conditions (*i.e.,* identification of the relevant market, unmet needs of current drugs in that market, and propensity of physician's to prescribe the new drug). To this end, *Linde*, because of the matter in which it deals, does not logically lend itself to the attention of an inventor of a quality management system and method for improving various product development launch practices occurring during a product development launch cycle. As is known to one of ordinary skill in the art, a product development launch cycle includes initial product planning, product design and development verification, process design and development verification, product and process validation and concludes with product launch.

No aspect of *Linde's* simulated market analysis would garner any consideration by an inventor of the present application because predicting future sales of an already developed drug, in order to identify how to best market the drug, is of no help or relevance to improving launch practices related to product design and development. Further, no useful observations can be gleaned from *Linde's* system employed to determine future market performance of drugs. As *Linde* discloses, information about three different market considerations are collected and assigned an estimated numerical value. Based on choices relating to latent needs of a particular drug, and the estimated numerical values obtained, the *Linde* system predicts the number of "captured" patients. Accordingly, *Linde* is merely a statistical analysis tool in which market data information is input providing the basis for calculations that subsequently return market share predictions.

Importantly, the "pre-launch choices" referred to in *Linde* are not remotely analogous to launch practices employed during product development as one of ordinary skill in the art would recognize. Rather, the *Linde's* pre-launch choices relate solely to marketing decisions of a manufactured drug, not considerations to be made during product development. Respectfully, the Examiner is reminded that "the scope of the claimed invention must be clearly

determined by giving the claims the 'broadest reasonable interpretation consistent with the specification'." MPEP § 2141 (citation omitted) (emphasis added).

Accordingly, *Linde* is not analogous prior art and cannot be relied upon for at least the reasons set forth above. In view of the foregoing, reversal of the obviousness rejections of claims 1-20 is respectfully requested, and the patentability of the claims confirmed.

A. Claims 1-2, 6 and 8-20 Are Patentable Under 35 U.S.C. § 103(a) Over The Proposed Combination of *Linde* and *Bieda*

Claims 1-2, 6 and 8-20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Linde* in view of *Bieda*. Appellants respectfully traverse the Examiner's rejection.

At the outset, Appellants reiterate that *Linde* is not analogous prior art for at least the reasons set forth above, and thus cannot be properly relied upon in making an obviousness rejection of claims 1-2, 6 and 8-20. Notwithstanding the inapplicability if *Linde*, the proposed combination of *Linde* and *Bieda* fails nonetheless.

The MPEP states that "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." MPEP §2143.03. (Citation omitted.) Moreover, it is axiomatic that in order to establish a *prima facie* case of obviousness, the cited references, when combined, must teach or suggest all of the claim limitations. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The MPEP further states the importance of "properly [communicating] the basis for a rejection so that the issues can be identified early and [Appellants] can be given a fair opportunity to reply." MPEP § 706.02(j). In doing so, an office action should set forth "the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate." *Id.*

1. Claim 1 Is Separately Patentable Under 35 U.S.C. § 103(a) Over *Linde* and *Bieda*

The proposed combination of *Linde* and *Bieda* does not teach or suggest the claimed invention. For instance, pending claim 1 recites the step of "determining a launch practice item based on a set of key sources, wherein the launch practice item is determined by a committee separate form the first and second launch program teams." As recited in claim 1, "[the] . . . launch practice [is] utilized in a product development launch cycle across a first launch program team during a first launch program and a second launch program team during a second launch program." Claim 1 further recites the step of "[an] . . . at least one member [of a second launch team] using [a] . . . launch practice item to improve consistency, deliverability and/or measurability of [a] . . . launch practice during [a] ... second launch program." *Linde* fails to teach, disclose or suggest these recitations of claim 1. For example, *Linde* does not teach, disclose or suggest the use of launch practice items to improve product development launch practices. Furthermore, *Linde* does not address launch practices utilized by a number of launch programs in a product development launch environment.

At best, *Linde* is limited to "a method for determining the post-launch performance of a product on a market." (Abstract.) While the claimed invention recites "improv[ing] . . . [a] launch practice during [a] . . . second launch program," *Linde*'s method is concerned with post-launch performance of a product after launch, i.e., after the drug has been manufactured and is now ready for sale. (¶ [0029].) For at least this reason, *Linde* does not teach, disclose or suggest pending claim 1.

Moreover, *Linde* is directed to predicting future market performance of a new drug based on an analysis of current market data relating to drugs already on the market for treating the same illness that the new drug is intended to treat. (e.g., ¶¶ [0080] - [0086].) The methods of obtaining the current market data are not changed, revised or improved from drug to drug. (e.g., ¶¶ [0058], [0076] and [0083].) Rather, it is the current market data obtained to provide a simulation of future market performance that varies from drug to drug. Thus, based

on the data collected from a target market for a new drug, a prediction of future market performance is obtained, which provides drug companies direction on how to best market the new drug. However, the current market data obtained for one new drug is inapplicable to the analysis of future market performance of another drug. *Linde* does not teach or suggest a method for improving a launch practice utilized in a product development launch cycle based on using a launch practice item to improve consistency, deliverability and/or measurability of the launch practice during a second launch program. Instead, the method of analysis in *Linde* remains the same, or unimproved, and the data used to obtain the prediction of future sales varies. Accordingly, there is no useful link between the analysis of one drug to another.

Bieda fails to cure the deficiencies of *Linde*. *Bieda* merely relates to an integrated failure mode effects and analysis (FMEA) tool for identifying and assessing severity of failures in order to prioritize corrective actions. (Abstract.) An effective corrective action taken for a particular failure may be noted and stored in the database as a lesson learned. (¶ [0025].) However, *Bieda* likewise fails to teach or suggest "determining a launch practice item . . . by a committee separate from the first and second launch program teams" and "transmitting the launch practice item to . . . the second launch program team."

Thus, the proposed combination of *Linde* and *Bieda* fails to teach or suggest each and every feature of pending claim 1. Accordingly, favorable reconsideration and reversal of the rejection of claim 1 and associated dependent claims under 35 U.S.C. §103(a) for at least the reasons set forth above is respectfully requested.

2. Claims 8, 12 And 16 Are Separately Patentable Under 35 U.S.C. § 103(a) Over *Linde* and *Bieda*

Claims 8, 12 and 16 recite substantially similar features and are believed to be allowable for at least the same reasons as set forth with regard to their respective base claims and further due to the additional features they recite. Separate and individual consideration is respectfully requested. For instance, claims 8, 12 and 16 require that "the launch practice item

is selected from the group consisting of launch elements, procedures, guidelines, standards, policies, and work instructions." Neither *Linde* nor *Bieda* teaches or suggests this feature.

Linde merely discloses that future market performance of drugs can be quantified using post-launch market information, information related to unmet needs on the drug market, and the propensity of physicians to prescribe particular drugs. (¶ [0029].) The post-launch market information collected, according to *Linde,* presupposes a drug already on the market (to the extent it has been fully developed and manufacturing has commenced), thus the launch phase has long been completed. Moreover, the market information according to *Linde* is exactly that – information or data on post-launch market performance to be plugged into an algorithm that provides future market predictions. (¶ [0030].) It is not a "launch practice item" used across multiple launch program teams during a product development launch cycle to "improve consistency, deliverability and/or measurability of the launch practice." To this end, the current market data collected according to *Linde* does not anticipate, in particular, "launch elements" (see Appellants' Specification, p. 6, ll. 11-21), "procedures" (*Id.*, p. 6, l. 22 to p. 7, l. 17), "guidelines" (*Id.*, p. 7, ll. 18-22), "standards" (*Id.*, p. 7, ll. 23-30), "policies" (*Id.*, p. 8, ll. 3-7), or "work instructions" (*Id.*, p. 7, l. 31 to p. 8, l. 2).

Linde fails to teach or suggest the features of claims 8, 12 and 16 regardless of the linguistic acrobatics the Examiner employs to support this overreaching rejection. (*See* Office Action, ¶ 18, pp. 12-13.) The Office is reminded that claims are to be interpreted *in light of the specification*. Not only does the Examiner's interpretation of the features of claims 8, 12 and 16 improperly stray from Appellants' specification, but it also makes little sense in light of *Linde*. Much like it is improper to construe a chair to include an airplane, information related to quantified unmet needs is not a standard simply because the Examiner says so. Moreover, *Bieda*, as the Examiner indicates, fails to cure the deficiencies of *Linde*.

Accordingly, favorable reconsideration and reversal of the rejection of claims 8, 12 and 16 under 35 U.S.C. §103(a) for at least the reasons set forth above is respectfully requested.

3. Claims 9, 13 And 17 Are Separately Patentable Under 35 U.S.C. § 103(a) Over *Linde* and *Bieda*

Claims 9, 13 and 17 recite substantially similar features and are believed to be allowable for at least the same reasons as set forth with regard to their respective base claims and further due to the additional features they recite. Separate and individual consideration is respectfully requested. For example, claims 9, 13 and 17 require that "the launch practice item is a procedure and a document supporting the procedure includes measurables and deliverables." Neither *Linde* nor *Bieda* teach or suggest this feature.

Linde merely discloses that the expected post-launch market performance resulting from a number of marketing choices can be simulated. (¶ [0086].) This combination of decisions fails to teach or suggest a "procedure," as recited in claims 9, 13 and 17. Procedures are put in place with the idea that they will be followed, thus ruling out decision-making. *Linde* instead is directed to determining which marketing choices can provide the best simulated marketing performance based on a formula as applied to current market data. The marketing choices made with respect to one marketed drug are inapplicable to the marketing choices made with respect to another drug. They certainly do not constitute a "procedure."

Moreover, *Linde* does not disclose or suggest a procedure including "measurables and deliverables." Contrary to the Examiner's contention, the disclosure of latent needs, target groups and market segments in *Linde* does not read upon the features of claims 9, 13 and 17. Rather, according to *Linde*, latent needs, target groups and market segments are choices a user can select when performing a market performance simulation. Thus, they are not "measurables and deliverables" identified by a launch practice procedure. *Bieda* fails to cure the deficiencies of *Linde*.

Accordingly, favorable reconsideration and reversal of the rejection of claims 9, 13 and 17 under 35 U.S.C. §103(a) for at least the reasons set forth above is respectfully requested.

4. Claims 10, 14 And 18 Are Separately Patentable Under 35 U.S.C. § 103(a) Over *Linde* and *Bieda*

Claims 10, 14 and 18 recite substantially similar features and are believed to be allowable for at least the same reasons as set forth with regard to their respective base claims and further due to the additional features they recite. Separate and individual consideration is respectfully requested. For example, claims 10, 14 and 18 require that "the launch practice item is a standard and a document supporting the standard includes information regarding how the launch practice should be performed." Neither *Linde* nor *Bieda* teaches or suggests this feature.

Linde merely discloses that a "key success factor" includes a physician's rationale (why, when, to whom, and how of prescribing the drug) for selecting a particular brand of drug. (¶ [0046].) Contrary to the Examiner's contention, the rationale behind a physician's drug prescription habits is wholly unrelated to launch practice standards that include information on how to perform a launch practice. The Examiner further states that the reasons behind a physician's choice of drug factors into the final drug product. (Office Action, p. 13.) There is absolutely no support for this contention. *Linde* does not even remotely disclose anything related to product (drug) development. Rather, *Linde* is wholly concerned with estimating future market performance of a drug based solely on marketing choices made in light of current market data obtained from similar drugs.

Accordingly, favorable reconsideration and reversal of the rejection of claims 10, 14 and 18 under 35 U.S.C. §103(a) for at least the reasons set forth above is respectfully requested.

5. Claims 11 and 15 Are Separately Patentable Under 35 U.S.C. § 103(a) Over *Linde* and *Bieda*

Independent claims 11 and 15 are each directed to an online system for facilitating improved consistency, deliverability and/or measurability of a launch practice utilized in a product development launch cycle across a first launch program team during a first launch program and a second launch program team during a second launch program. Likewise, claims 11 and 15 recite substantially similar features. However, the proposed combination of *Linde* and *Bieda* fails to teach or suggest the features of independent claims 11 and 15. For instance, claim 11 recites the feature of at least one server computer configured to "during the first launch program, transmit a launch practice item to an at least one member of the first launch program team, wherein the at least one member uses the defined launch practice item to improve consistency, deliverability and/or measurability of the launch practice."

Linde simply discloses that a medical marketing company provides insight into market performance to their clients, which may include medical companies, drug manufacturers and research centers. (¶ [0033].) *Linde* particularly fails to disclose transmitting the "launch practice item," as the Examiner contends, "to an at least one member of the first launch program team." Rather, *Linde* merely discloses that the information gathered by the medical marketing company is provided to a client for use in simulating post-launch performance. An "at least one member of the first launch program team" has little use for this information since it does not influence the improvement of launch practices for product launch programs along a product development launch cycle.

Moreover, the information provided by the medical marketing company, a third-party, is merely marketing data related to a specific drug that is inapplicable to predicting future market performance of other non-related drugs produced by the pharmaceutical manufacturer. The marketing data is not a launch practice item used to improve consistency, deliverability and/or measurability of the launch practice "in a product development launch cycle across a first launch program team during a first launch program and a second launch program team during

a second launch program," as recited in claim 11. Rather, the marketing data is data corresponding to a current drug that is plugged into an algorithm for predicting future sales of an alternative/substitute drug. As such, *Linde* fails to disclose or suggest at least the aforementioned feature of "during the first launch program, transmit a launch practice item to an at least one member of the first launch program team, wherein the at least one member uses the defined launch practice item to improve consistency, deliverability and/or measurability of the launch practice," recited in claim 11. *Bieda* likewise fails to disclose this feature and, thus, does not cure the deficiencies of *Linde*.

Claim 11 further recites that the at least one server computer is configured to "receive an at least one member observation regarding the launch practice item from the at least one member of the first launch program team." *Linde* also fails to teach or suggest this claim limitation. Rather, *Linde* merely discloses that market performance data is gathered by interviewing physicians from a target group and monitoring their drug prescription and purchase patterns. (¶ [0050].) No observations regarding the launch practice item are received by a member of a *launch program team*, as is recited by claim 11. Moreover, *Linde* discloses that the market data is gathered by a medical marketing company as a service provided to drug manufacturers.

To the extent the Examiner contends that "an at least one member observation" is not the observation of a group of physicians regarding their prescription patterns, but is rather the observation of a medical marketing company of the observations of the physicians interviewed regarding their prescription patterns, the contention is also flawed. The medical marketing company provided in *Linde* cannot both "transmit a launch practice item to an at least one member of the first launch program team" and also be "an at least one member of the first launch program team" providing an at least one member observation, as recited in claim 11. Moreover, *Bieda* fails to cure the deficiencies of *Linde*.

Furthermore, claim 11 recites that the at least one server computer is configured to "transmit a revised launch practice item and/or a new launch practice item implementing the at least one member observation . . . if implementing the observation improves the consistency, deliverability and/or measurability of the launch practice." The Examiner notes that *Linde* fails to teach or suggest this feature, but contends that the deficiencies of *Linde* are resolved by *Bieda*. Appellants respectfully disagree. Instead, *Bieda* merely discloses storing lessons learned during a product performance analysis and risk assessment of product failure modes. (¶ [0025].) However, *Bieda* does not disclose transmitting a revised launch practice item and/or new launch practice item implementing the lessons learned to an at least one member of the second launch program team.

Thus, the proposed combination of *Linde* and *Bieda* fails to teach or suggest each and every feature of pending claim 11. Moreover, the proposed combination likewise fails to teach or suggest the features of independent claim 15 to the extent they are substantially similar to those of claim 11. Accordingly, favorable reconsideration and reversal of the rejection of claims 11 and 15 and their associated dependent claims under 35 U.S.C. §103(a) for at least the reasons set forth above is respectfully requested.

B. Claims 3-5 Are Patentable Under 35 U.S.C. § 103(a) Over The Proposed Combination of *Linde*, *Bieda* And *Jordan Kogler*

Claims 3-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Linde* and *Bieda* in further view of *Jordan Kogler*. For at least the following reasons, Appellants respectfully traverse this rejection.

The MPEP states that in order to rely on a reference under 35 U.S.C. § 103, it must be analogous prior art. MPEP § 2141.01(a). Thus, the reference must be in the field of Appellants' endeavor, or if "in a field different from that of [Appellants'] endeavor . . . is one which, because of the matter with which it deals, logically would have commended itself to an

inventor's attention in considering [the] invention as a whole." *Id.* In that regard, *Jordan Kogler* does not constitute analogous prior art.

In particular, the present application is directed to a quality management system for use during a product development launch cycle. One of ordinary skill in the art, particularly in the automotive industry referred to in the background, would recognize that a product development launch cycle corresponds to a timeline over which a new product or program (*e.g.*, new vehicle) is initially planned and defined up to its full production launch. The product development launch cycle includes several phases, such as planning, product design and development verification, process design and development verification, product and process validation and launch. Each phase consists of several key milestones, including kick-off (KO), strategic intent (SI), program approval (PA), product readiness (PR), change cutoff (CC), launch ready (LR), launch sign-off (LS) and final sign-off (FS), or the like. A product development launch cycle includes launch elements, which correspond to tasks or events relating to product development, that require completion prior to the start of production and are characterized by where they fall on the product development launch cycle. As one of ordinary skill in the art would recognize, product launch elements may cover aspects such as supplier sourcing, design robustness, design testing and specification compliance, production process design, quality inspection standards, process capability, production capacity, product packaging, product testing and operator training, to name a few.

Quality management systems targeting the product development launch cycle provide a framework of policies, procedures, processes and techniques used in planning, developing and ultimately launching products in industry. The aim is to ensure products are designed and produced to meet or exceed customer requirements, by embedding awareness of quality in organizational processes within the project management framework. To this end, launch program teams - dedicated to a particular product, group of products or program - made up of design and product engineers, quality control personnel, manufacturing personnel, buyers,

and program managers are enlisted to seeing a program through the planning phase to the launch phase. Various launch practices are employed and/or utilized by launch program teams during the product development launch cycle to attain the various engineering, manufacturing and purchasing milestones using a disciplined approach, which is aimed at quality control to ensure products are designed and produced to meet or exceed customer requirements. In that regard, the present application is directed to an online system and method for facilitating improved consistency, deliverability and/or measurability of these launch practices.

Jordan Kogler, on the other hand, is a non-analogous reference about marketing strategy. *Jordan Kogler* relates to the field of product marketing, namely the marketing of financial services to a targeted customer base. *Jordan Kogler* provides a system and method of acquiring new customers for secondary products through channels opened by the direct marketing of primary products. (Abstract.) Thus, *Jordan Kogler* is not in the field of Appellants' endeavor. Moreover, *Jordan Kogler* is not reasonably pertinent to the particular problem with which Appellants are concerned, thus commending itself to the Appellants' attention. There are no aspects of the *Jordan Kogler* strategic marketing system and method that is of any relevance to Appellants' concern for facilitating improved product development launch practices.

Accordingly, *Jordan Kogler* is not analogous prior art and cannot be relied upon for at least the reasons set forth above. Reversal of the obviousness rejections of claims 3-5 is respectfully requested, and the patentability of the claims confirmed.

Notwithstanding the inapplicability if *Jordan Kogler* as non-analogous art, the proposed combination of *Linde*, *Bieda* and *Jordan Kogler* fails nonetheless because the asserted references do not teach or suggest pending claims 3-5.

1. Claim 3 Is Separately Patentable Under 35 U.S.C. § 103(a) Over The Proposed Combination of *Linde*, *Bieda* And *Jordan Kogler*

Claim 3 is believed to be allowable for at least the same reasons as set forth with regard to its respective base claims and further due to the additional features it recites. Separate and individual consideration is respectfully requested. For example, claim 3 requires "deciding to revise the launch practice item or to create a new launch practice item if implementing the at least one member observation improves the consistency, deliverability and/or measurability of the launch practice." Per the Examiner, neither *Linde* nor *Bieda* teaches or suggests this feature. (Office Action, p. 19.) Contrary to the Examiner's contention, however, *Jordan Kogler* fails to cure the deficiencies of *Linde* and *Bieda*.

To this end, *Jordan Kogler* merely discloses that a marketing agent uses customer information to analyze the marketing strategy of a credit card company to determine which credit card offers garner greater customer acceptance. (¶ [0069].) The marketing agent may then refine the customer offers to maximize product acceptance. *Id.* *Jordan Kogler* does not disclose or suggest any decision-making regarding product launch practices, especially if implementing a program launch team member's observation improves a launch practice.

Accordingly, favorable reconsideration and reversal of the rejection of claim 3 under 35 U.S.C. §103(a) for at least the reasons set forth above is respectfully requested.

2. Claim 4 Is Separately Patentable Under 35 U.S.C. § 103(a) Over The Proposed Combination of *Linde*, *Bieda* And *Jordan Kogler*

Claim 4 is believed to be allowable for at least the same reasons as set forth with regard to its respective base claims and further due to the additional features it recites. Separate and individual consideration is respectfully requested. For example, claim 4 requires "transmitting the revised launch practice item or the new launch practice item to the at least one member of the second launch program team." It should be noted that the Examiner concedes that *Linde* and *Jordan Kogler* do not teach or suggest this feature. However, contrary to the

Examiner's contention, *Bieda* fails to cure the deficiencies of *Linde* and *Jordan Kogler*. Instead, *Bieda* merely discloses storing lessons learned during a product performance analysis and risk assessment of product failure modes. (¶ [0025].) *Bieda* does not disclose transmitting the revised launch practice item or the new launch practice item to an at least one member of the second launch program team.

Accordingly, favorable reconsideration and reversal of the rejection of claim 4 under 35 U.S.C. §103(a) for at least the reasons set forth above is respectfully requested.

C. Claim 7 Is Patentable Under 35 U.S.C. § 103(a) Over *Linde*

Claim 7 is believed to be allowable for at least the same reasons as set forth with regard to its respective base claims and further due to the additional features it recites. Separate and individual consideration is respectfully requested. For example, claim 7 recites "wherein the set of key sources further includes launch principles, assembly plant launch process models, product quality planning initiatives, former body and assembly quality systems, former production systems, milestone standards, and product development systems." Since *Linde* fails to teach or suggest this feature, Appellants respectfully traverse.

Instead, *Linde* merely discloses obtaining information regarding the reasons physicians choose to prescribe a particular drug on the market. (¶ [0050].) *Linde* also discloses qualitative marketing efforts tending to affect the adoption of a drug by a physician as a "drug of choice." (¶ [0051].) In fact, all of the post-launch market performance analysis activities disclosed by *Linde* have nothing in common with the product launch development process, and thus fail to render claim 7 obvious in view of *Linde*. Notably, the Examiner's comparison of product *quality* planning initiatives with *Linde's* disclosure of *qualitative* marketing efforts simply because the emphasized words sound similar is wholly improper. (*See* Office Action, p. 23.) Moreover, Appellants' find the Examiner's assertion that "paragraph 46 [of *Linde*] teaches the why, when, to whom and how of launching the product" disingenuous. *Id.* Rather, paragraph

46 refers to identifying rationales for *why physicians choose to prescribe a particular drug on the market.* (¶ [0046].)

Accordingly, favorable reconsideration and reversal of the rejection of claim 7 under 35 U.S.C. §103(a) for at least the reasons set forth above is respectfully requested.

D. CONCLUSION

In view of the foregoing, Appellants believe that all formal and substantive requirements for patentability have been met, and that this application is in condition for allowance. Accordingly, Appellants respectfully request that the Board reverse the above-identified rejections for at least the reasons set forth above to properly advance the prosecution of this application.

The fee of $510 as applicable under the provisions of 37 C.F.R. § 41.20(b)(2) is being charged to Deposit Account No. 06-1510 via electronic authorization submitted concurrently herewith. The Commissioner is hereby authorized to charge any additional fees or credit any overpayments as a result of the filing of this paper to Deposit Account No. 06-1510.

Respectfully submitted,

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Enclosure - Appendices

VIII. CLAIMS APPENDIX

1. An online method for facilitating improved consistency, deliverability and/or measurability of a launch practice utilized in a product development launch cycle across a first launch program team during a first launch program and a second launch program team during a second launch program, the online method comprising:

determining a launch practice item based on a set of key sources, wherein the launch practice item is determined by a committee separate from the first and second launch program teams;

transmitting the launch practice item to an at least one member of the second launch program team; and

the at least one member of the second launch program team using the launch practice item to improve consistency, deliverability and/or measurability of the launch practice during the second launch program.

2. The online method of claim 1 further comprising receiving an at least one member observation regarding the launch practice item from at least one member of the first launch program team.

3. The online method of claim 2 further comprising deciding to revise the launch practice item or to create a new launch practice item if implementing the at least one member observation improves the consistency, deliverability and/or measurability of the launch practice.

4. The online method of claim 3 further comprising transmitting the revised launch practice item or the new launch practice item to the at least one member of the second launch program team.

5. The online method of claim 4 wherein the transmitting step includes updating an at least one server computer and notifying the at least one member of the second launch program team.

6. The online method of claim 1 wherein the set of key sources includes lessons learned from an at least one member of the first or second launch program team.

7. The online method of claim 6 wherein the set of key sources further includes launch principles, assembly plant launch process models, product quality planning initiatives, former body and assembly quality systems, former production systems, milestone standards, and product development systems.

8. The online method of claim 1 wherein the launch practice item is selected from the group consisting of launch elements, procedures, guidelines, standards, policies, and work instructions.

9. The online method of claim 8 wherein the launch practice item is a procedure and a document supporting the procedure includes measurables and deliverables.

10. The online method of claim 8 wherein the launch practice item is a standard and a document supporting the standard includes information regarding how the launch practice should be performed.

11. An online system for facilitating improved consistency, deliverability and/or measurability of a launch practice utilized in a product development launch cycle across a first launch program team during a first launch program and a second launch program team during a second launch program, the system comprising at least one server computer operably serving at least one client computer, the at least one server computer configured to:

(i) during the first launch program, transmit a launch practice item to an at least one member of the first launch program team, wherein the at least one member uses the defined launch practice item to improve consistency, deliverability and/or measurability of the launch practice;

(ii) receive an at least one member observation regarding the launch practice item from the at least one member of the first launch program team; and

(iii) transmit a revised launch practice item and/or a new launch practice item implementing the at least one member observation to an at least one member of the second launch program team before the end of the second launch program if implementing the observation improves the consistency, deliverability and/or measurability of the launch practice.

12. The system of claim 11 wherein the launch practice item is selected from the group consisting of launch elements, procedures, guidelines, standards, policies, and work instructions.

13. The system of claim 11 wherein the launch practice item is a procedure and a document supporting the procedure includes measurables and deliverables.

14. The system of claim 11 wherein the launch practice item is a standard and a document supporting the standard includes information regarding how the launch practice should be performed.

15. An online system for facilitating improved consistency, deliverability and/or measurability of a launch practice utilized in a product development launch cycle across a first launch program team during a first launch program and a second launch program team during a second launch program, the system comprising:

(i) a means for transmitting a launch practice item to an at least one member of the first launch program team during the first launch program, wherein the at least one member

uses the defined launch practice item to improve consistency, deliverability and/or measurability of the launch practice;

(ii) a means for receiving an at least one member observation regarding the launch practice item from the at least one member of the first launch program team; and

(iii) a means for transmitting a revised launch practice item and/or a new launch practice item implementing the at least one member observation to an at least one member of the second launch program team before the end of the second launch program if implementing the observation improves the consistency, deliverability and/or measurability of the launch practice.

16. The system of claim 15 wherein the launch practice item is selected from the group consisting of launch elements, procedures, guidelines, standards, policies, and work instructions.

17. The system of claim 15 wherein the launch practice item is a procedure and a document supporting the procedure includes measurables and deliverables.

18. The system of claim 15 wherein the launch practice item is a standard and a document supporting the standard includes information regarding how the launch practice should be performed.

19. The online method of claim 1further comprising receiving the set of key sources from an at least one member of the first launch program team.

20. The online method of claim 1 further comprising:

transmitting the launch practice item to an at least one member of the first launch program team; and

the at least one member of the first launch program team using the launch practice item to improve consistency, deliverability and/or measurability of the launch practice during the first launch program.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.